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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,151	04/16/2002	Takashi Shigematsu	13723-002001	8643

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EXAMINER	
LUM, LEON YUN BON	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,151	SHIGEMATSU ET AL.	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-27,29-60 and 62-64* is/are pending in the application.

4a) Of the above claim(s) *22-26 and 30-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27,29,58-60 and 62-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed May 22, 2006 is acknowledged and has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kamarei (US 4,749,522) in view of Proksch et al (US 4,216,117).

Kamarei reference teaches that prior to an extraction process isolating biomolecules from tissue, various methods in combination can be performed to the tissue, wherein two such methods in combination can be freeze-thaw treatment and freeze-drying. See column 8, lines 39-43 and 51-52. In addition, Kamarei teaches that the tissue can be blood plasma (i.e. solution containing lipoprotein) and the biomolecule is lipoprotein. See column 6, line 32 and column 7, line 64. While the reference itself is directed towards a supercritical fluid extraction process, the reference sufficiently discloses teaching of steps that anticipate the instant claims. For example, the combination of the freeze-thaw and freeze-drying processes would necessarily have to be performed in the order of (1) freeze-thaw and then (2) freeze-drying (i.e. freezing and melting a solution containing lipoprotein; freeze-drying the melted solution), since the opposite order produces dried material that lacks water in order to perform the thawing process. Furthermore, although Kamarei teaches numerous biomolecules that can individually be isolated from numerous tissue types, the disclosure of many embodiments does not necessarily render the reference as incapable of performing the claimed limitation. In fact, the courts have stated that, "the prior art's mere disclosure of

more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

In the instant reference, the step of applying biological tissue samples to either freeze-thawing or freeze-drying are well known to one of ordinary skill in the art. Since blood plasma is one type of tissue that can be frozen, one of ordinary skill in the art would recognize that blood plasma could be chosen as a tissue to perform the necessarily sequential steps of freeze-thawing and freeze-drying. The instant claim is therefore anticipated.

However, Kamarei fails to teach the step of determining an amount of the denatured lipoprotein in the powder.

Proksch et al teach the step of measuring lipoprotein reconstituted in serum, in order to produce accurate lipoprotein diluents that act as standards for lipoprotein assays. See column 3, lines 9-18; column 9, lines 19-38; and column 10, lines 14-42.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Kamarei with the step of measuring lipoprotein reconstituted in serum, as taught by Proksch et al, in order to produce accurate lipoprotein diluents that act as standards for lipoprotein assays. The creation of a standard allows measurement of absolute lipoprotein values in an assay, thereby providing motivation to combine Kamarei and Proksch et al methods. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable

expectation of success in combining the step of Proksch et al with the method of Kamarei, since Kamarei teach lyophilized lipoprotein, and Proksch et al requires lyophilized lipoprotein to produce the standard.

6. Claim 27, 29, 58-60, and 62-64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Magneson et al (US 5,547,873) in view of Proksch et al (US 4,216,117).

Magneson et al reference teaches the method of preparing stabilizing proteins for long term dry storage, by teaching the sequential steps of adding anti-coagulant solution to a sample of blood plasma (i.e. adding an anti-coagulating agent preceding the freezing step), subjecting the blood plasma to several freeze/thaw processes (i.e. freezing and melting a solution containing lipoprotein), and then lyophilizing the blood plasma after the last thawing step (i.e. freeze-drying the melted solution of lipoprotein), wherein the lyophilized product contains LDL. See column 2, lines 39-44; column 4, line 30 to column 5, line 18; and Table 1.

However, Magneson et al fail to teach the step of determining an amount of the denatured lipoprotein in the powder.

Proksch et al teach the step of measuring lipoprotein reconstituted in serum, in order to produce accurate lipoprotein diluents that act as standards for lipoprotein assays. See column 3, lines 9-18; column 9, lines 19-38; and column 10, lines 14-42.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Kamarei with the step of measuring lipoprotein

reconstituted in serum, as taught by Proksch et al, in order to produce accurate lipoprotein diluents that act as standards for lipoprotein assays. The creation of a standard allows measurement of absolute lipoprotein values in an assay, thereby providing motivation to combine Kamarei and Proksch et al methods. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in combining the step of Proksch et al with the method of Kamarei, since Kamarei teach lyophilized lipoprotein, and Proksch et al requires lyophilized lipoprotein to produce the standard.

With respect to claim 58, Magneson et al teach that trehalose or sucrose sugar (i.e. stabilizing agent) is added to thawed blood plasma solution prior to lyophilization (i.e. following the melting step), wherein the resulting reconstituted lipoprotein solutions have improved optical clarity over control solutions without the sugars. See column 5, lines 3-7 and Table 1.

With respect to claim 63, Magneson et al teach the blood plasma includes serum. See column 2, lines 34-38.

Response to Arguments

7. Applicants' arguments with respect to claims 27, 29,58-60, and 62-64 in the response filed May 22, 2006 have been considered but are moot in view of the new ground(s) of rejection.

However, Applicants' arguments on page 10, 5th paragraph to page 11, 2nd paragraph of the response addresses a point that is not covered by the new grounds of rejection, and is therefore considered.

Specifically, Applicants contend that since Magneson et al disclose a method that results in a preservation of lipoprotein's structural integrity, the reference cannot teach the claimed method of a denatured lipoprotein. See especially page 10, last paragraph.

Applicants' arguments have been fully considered but are not persuasive. Because Magneson describes a method with ***exactly the same steps*** as the claimed invention, one of ordinary skill in the art following the disclosed steps would necessarily perform the claimed invention and arrive at the same end result. It may be possible that both denatured and native conformations are present in the end product, which may explain the differences. However, in comparing the specification to Magneson et al, it is clear that the same method steps are being performed between the two disclosures, thereby preventing the instant invention from being free of the prior art. For example, the specification explicitly states that lipoproteins are denatured through at least one freezing process. See page 7, lines 20-24; page 19, line 31 to page 20, line 3; and especially page 22, lines 16-24, which states "In the second mode of embodiment, the process including the ***step for freezing <u>for the purpose of denaturing lipoprotein</u>*** is required to be performed at least one and, when necessary, may be repeated." The specification therefore indicates that multiple freeze-thaw processes are included in its definition of freezing for the purpose of denaturing lipoprotein. Following the "second aspect", the specification teaches a "third aspect" of freeze-drying the thawed

lipoprotein. See page 24, lines 3-7. The complete method step, as disclosed by the specification, therefore combines a freeze/thaw stage followed by a freeze-drying state. Furthermore, the specification and Applicants have not provided empirical evidence that the specific steps of the instant invention would produce an end product that is different from that of the prior art.

Since Magneson et al teach specifically the step of "subjecting the blood plasma to several freeze/thaw processes" followed by the step of lyophilizing the sample after the last thaw, it is clear that both the specification and Magneson et al teach the exact same steps. As stated above, although the end products of the two disclosures are stated to be different (i.e. native structure vs. denatured), because the steps of the two disclosures are exactly the same, one of ordinary skill in the art practicing Magneson et al's method would directly practice the method of the instant invention and arrive at the same result.

Conclusion

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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